

REMARKS

The Office Action of October 24, 2008 has been received and carefully reviewed. It is submitted that, by this Amendment, all bases of rejection and objection are traversed and overcome. Upon entry of this Amendment, claims 1-44 and 46-48 remain in the application. Claim 45 is canceled herein. Reconsideration of the claims is respectfully requested.

At the outset, claims 1, 5, 9, 10, 11, 12, 20, 28, 35, 37-39, and 42 have been amended in order to correct minor grammatical and/or formatting errors, and/or to improve the readability of the claim.

Submitted herewith are electronic copies of all of the non-patent literature cited in the information disclosure statement dated February 11, 2004. It is submitted that these copies were not required, as they had been cited by or to the PTO in the parent application; however, the copies are being provided here for the Examiner's convenience and to comply with the Examiner's request.

The specification is objected to because of several alleged informalities. The specification has therefore been amended to i) update the continuing data of the patent application, ii) to fix any irregularities that "caused" the transfer of the specification as filed to the published version, and iii) any typographical errors found throughout Applicants' specification as filed. It is to be understood that the changes set forth above for various paragraphs of Applicants' specification are referenced both by paragraph number of the published application and page/line number of the specification as filed because some of the errors were evident on the published application, but **not** on Applicants' specification as filed (due to the PTO's transfer of the application to the published version (as noted by the Examiner in the instant Office Action)).

Claims 1, 3, 11, 12, 22, and 42 are objected to also because of informalities. Claims 1, 3, 22, and 42 have been amended according to the Examiner's suggestions and/or to clarify the claim. It is therefore submitted that the instant objection to these claims has been obviated in light of the amendments, and withdrawal of the same is respectfully requested.

Regarding claims 11 and 12, the Examiner asserts that it is unclear what structural limitations are set forth in these claims. The Examiner further asserts that the claims merely define an intended use of the device. Applicants submit, however, that the claims provide structural limitations of i) the visually opaque substance into which the device is adapted to be inserted (claim 11), and ii) the anatomical structure visualized (claim 22). Applicants respectfully disagree that the claims merely recite the intended use. Applicants therefore respectfully request that the Examiner withdraw the objection.

Claims 1-48 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. With respect to claims 24, 26, and 30, the Examiner asserts that it is unclear how the imaging material can be a CT or MR contrast agent or ultrasound imaging material when the respective independent claims recite that the imaging material is a radiopharmaceutical material suitable for producing an image detectable by PET or SPECT.

At the outset, Applicants point out that claims 1-23, 28, 29, and 32-48 do not include the allegedly confusing language set forth by the Examiner. As such, Applicants submit that the rejection of at least claims 1-23, 28, 29, and 32-48 is erroneously based, and withdrawal of the same is respectfully requested.

Furthermore, claims 24, 26, and 30 have been amended herein to more particularly point out and distinctly claim that which Applicants regard as their invention. Claim 24 has been amended to recite a second imaging material comprising a CT contrast agent. Claim 26 has been amended to recite a second imaging material comprising an MRI contrast agent. Claim 30 has been amended to recite a second imaging material comprising CT contrast agents, MRI contrast agents, and/or ultrasound imaging materials. Support for the new recitations in claims 24, 26, and 30 may be found throughout Applicants' specification as filed, at least at page 6, lines 16-18 and page 12, line 18 through page 13, line 2.

In light of the above arguments and the amendments made to claims 24, 26 and 30, Applicants submit that the instant rejection under 35 U.S.C. § 112, second paragraph, is erroneously based and/or has been traversed and overcome, and withdrawal of the same is respectfully requested.

Claims 1-9, 11-15, 17-23, and 26-37 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ratner (U.S. Patent No. 5,154,179) in view of Filler (U.S. Patent No. 5,948,384). The Examiner asserts that Ratner discloses all of the elements of independent claims 1, 20, and 28, except for using a radiopharmaceutical material as an imaging material that is detectable by positron emission tomography and/or single photon emission computed tomography. The Examiner relies on Filler to supply the noted deficiency of Ratner. The Examiner concludes that it would have been obvious to modify Ratner's visibility enhancement device and use radioisotopes that decay and are detectable by a single photon emission computed tomography as taught by Filler to obtaining better image contrast.

The Applicants respectfully disagree with the Examiner's instant 35 U.S.C. § 103(a) rejection. Independent claims 1 and 28 have been amended herein for further clarification. Amended claims 1 and 28, and claim 20 as originally filed, recite, in some form, that the **imaging material** (which **contains** at least one radiopharmaceutical material) produces an image detectable in at least one of positron emission tomography or single photon emission computed tomography.

Ratner discloses a device that may be inserted into a body subjected to **magnetic resonance imaging**, where the device carries a material exhibiting a characteristic under magnetic resonance imaging that differs substantially from that of the body so that the visibility of the member under magnetic resonance imaging is enhanced (see abstract of Ratner). The imaging material carried by the device may be selected from ferromagnetic materials (see column 4, lines 24-28) and paramagnetic substances selected from gadolinium, chromium, nickel, copper, iron, and manganese (see column 6, lines 34-47). In an embodiment, non-paramagnetic substances may be used, where such substances have desirable relaxation times and may be used in a

separate lumen of the device to make the device ***detectable by magnetic resonance imaging*** (see column 6, lines 48-54). Ratner further discloses that the material may also be formed of a material that is relatively radiopaque so that it can be observed under x-rays (see column 9, lines 4-8). In sharp contrast to Applicants' claims 1, 20, and 28, Ratner discloses that such materials are ***also*** more visible under magnetic resonance. In other words, the imaging material defined in claims 1, 20, and 28 is detectable under i) positron emission tomography, and/or ii) single photon emission computed tomography; whereas the imaging material of Ratner is ***also detectable under magnetic resonance***.

Further, Applicants submit that the Ratner device is designed to facilitate magnetic resonance imaging. Accordingly, the materials listed hereinabove are those that are typically used to produce such images. Despite the fact that Ratner discloses that other contrast agents (such as a radiopaque material) may be used, such contrast agents are used ***in addition*** to the material selected for producing magnetic resonance images. For example, the radiopaque material may be impregnated into the magnetic imaging material (see column 9, lines 15-18). Such impregnated materials may be visible under ***both*** magnetic resonance imaging and x-rays.

The Examiner turns to Filler to establish using radiopharmaceutical materials as a suitable imaging material that may be detectable under i) positron emission tomography, and/or ii) single photon emission computed tomography. The Filler reference is directed to particulate agents for use in diagnostics and therapy, including diagnostic imaging (see column 1, lines 5-8). An example of a particulate agent includes particles incorporating gamma or electron emitter radionuclide, and may be detectable by gamma detectors, scintigraphy or SPECT (see column 3, lines 63-67). Applicants submit that Filler ***neither*** discloses nor suggests that such particulate agent may be used in a device configured for visualizing a structure located inside a body.

Additionally, given the fact that Ratner discloses a device configured for magnetic resonance imaging, it is submitted that one skilled in the art would ***not*** turn to the teachings of Filler to use a particulate agent designed for, e.g., SPECT; and not

magnetic resonance. In fact, such particulate agents are **not** used for magnetic resonance imaging. Although Ratner discloses that other contrast agents (such as a radiopaque material) may be impregnated in the device material, the impregnated material is still viewable under magnetic resonance. It is therefore submitted that one skilled in the art would find **no** motivation to combine the references.

For all of the reasons stated above, it is submitted that the combination of Ratner and Filler **fails** to render obvious independent claims 1, 20, and 28. As such, it is further submitted that Applicants' invention as defined in independent claims 1, 20, and 28, and in those claims depending ultimately therefrom, is not anticipated, taught or rendered obvious by Ratner and Filler, either alone or in combination, and patentably defines over the art of record.

Claims 10 and 38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ratner in view of Filler, and further in view of Valley, et al. (U.S. Patent No. 5,766,151). For all of the reasons stated above, it is submitted that the combination of Ratner and Filler fails to teach all of the elements of independent claims 1 and 28, from which claims 10 and 38 depend, respectively. Applicants further submit that Valley fails to supply the deficiencies of Ratner and Filler. As such, it is submitted that claims 10 and 38 are also patentable because of their dependency upon claims 1 and 28, respectively. Accordingly, it is further submitted that Applicants' invention as defined in claims 10 and 38 is not anticipated, taught, or rendered obvious by Ratner, Filler, and Valley, either alone or in combination, and patentably defines over the art of record.

Claims 16, 24, and 25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ratner in view of Filler, and further in view of Unger, et al. (U.S. Patent No. 5,736,121). For all of the reasons stated above, it is submitted that the combination of Ratner and Filler fails to teach all of the elements of independent claim 1 (from which claim 16 depends) and independent claim 20 (from which claims 24 and 25 depend), and Unger fails to supply the deficiencies of Ratner and Filler. As such, it is submitted that claim 16 is patentable because of its dependency upon claim 1; and claims 24 and 25 are patentable because of their dependency upon claim 20.

Accordingly, it is further submitted that Applicants' invention as defined in claims 16, 24, and 25 is not anticipated, taught, or rendered obvious by Ratner, Filler, and Unger, either alone or in combination, and patentably defines over the art of record.

Claims 39, 40, 41, 43, 47, and 48 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ratner in view of Miller, et al. (U.S. Patent No. 6,226,418). The Examiner asserts that Ratner discloses all of the elements of independent claim 39, except for registering a first and second image. The Examiner relies on Miller to supply the deficiency of Ratner. The Examiner concludes that the combination of Ratner and Miller renders obvious independent claim 39.

Although Applicants do not acquiesce to the Examiner's rejection, in order to expedite prosecution, independent claim 39 has been amended to recite, "registering a first image with a second image, wherein ***the first image is derived from at least one of PET or SPECT, and the second image is derived from at least one of MRI, CT, and ultrasound...***" Support for this new recitation may be found in Applicants' specification as filed, at least at page 39, lines 16-19. Claim 45 has been canceled in light of the foregoing amendment to claim 39.

Miller discloses an apparatus and method for image registration of an image having a large deformation. The method is based on information about various substructures of a template and a target image, and varying degrees of knowledge about the substructures derived from anatomical imagery acquired from modalities like CT, MRI, functional MRI, PET, ultrasound, SPECT, MEG, EEG, or cryosection (see column 6, lines 42-49; and column 27, lines 6-13). Applicants submit that the operator "or" indicates that the information about the substructures is based on, e.g., CT (alone), MRI (alone), ultrasound (alone), etc. In other words, Miller does ***not*** disclose or even suggest that image registration may be accomplished using information from a mixture of modalities such as, e.g., a first image derived from SPECT and a second image derived from MRI (as similarly recited in independent claim 39).

For the reason stated above, Applicants submit that the combination of Ratner and Miller ***fails*** to teach all of the elements of amended claim 39. As such, it is

submitted that Applicants' invention as defined in independent claim 39, and in those claims depending ultimately therefrom, is not anticipated, taught, or rendered obvious by Ratner and Miller, either alone or in combination, and patentably defines over the art of record.

Claim 42 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Ratner in view of Miller, and further in view of Driscoll, Jr., et al. (U.S. Patent No. 5,067,162). For the reasons stated above, it is submitted that the combination of Ratner and Miller fails to teach all of the elements of independent claim 39, from which claim 42 depends. Applicants further submit that Driscoll fails to supply the deficiencies of Ratner and Miller. As such, it is submitted that claim 42 is also patentable because of its dependency upon claim 39. Accordingly, it is submitted that Applicants' invention as defined in claim 42 is not anticipated, taught, or rendered obvious by Ratner, Miller, and Driscoll, either alone or in combination, and patentably defines over the art of record.

Claim 44 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Ratner in view of Miller, and further in view of Chaney, et al. (U.S. Patent No. 5,926,568). For the reason stated above, it is submitted that the combination of Ratner and Miller fails to teach all of the elements of independent claim 39, from which claim 44 depends. Applicants further submit that Chaney fails to supply the deficiencies of Ratner and Miller. As such, it is submitted that claim 44 is also patentable because of its dependency upon claim 39. Accordingly, it is submitted that Applicants' invention as defined in claim 44 is not anticipated, taught, or rendered obvious by Ratner, Miller, and Chaney, either alone or in combination, and patentably defines over the art of record.

Claim 45 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Ratner in view of Miller, and further in view of Engdahl, et al. (U.S. Patent No. 6,303,935). Applicants submit, however, that the instant rejection is moot in light of the cancellation of claim 45 herein.

Claim 46 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Ratner in view of Miller, and further in view of Chaney. For the reason stated above, it is submitted that the combination of Ratner and Miller fails to teach all of the elements

of independent claim 39, from which claim 46 depends. Applicants further submit that Chaney fails to supply the deficiencies of Ratner and Miller. As such, it is submitted that claim 46 is patentable at least because of its dependency upon claim 39. Accordingly, it is submitted that Applicants' invention as defined in claim 46 is not anticipated, taught, or rendered obvious by Ratner, Miller, and Chaney, either alone or in combination, and patentably defines over the art of record.

In summary, claims 1-44 and 46-48 remain in the application. It is submitted that, through this Amendment, Applicants' invention as set forth in these claims is now in a condition suitable for allowance.

Further and favorable consideration is requested. If the Examiner believes it would expedite prosecution of the above-identified application, the Examiner is cordially invited to contact Applicants' Attorney at the below-listed telephone number.

Respectfully submitted,

DIERKER & ASSOCIATES, P.C.

/Julia Church Dierker/

Julia Church Dierker
Attorney for Applicants
Registration No. 33368
(248) 649-9900, ext. 25
juliad@troypatent.com

3331 West Big Beaver Rd., Suite 109
Troy, Michigan 48084-2813
Dated: February 24, 2009
JCD/AMS/JRK